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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,591	07/25/2003	Andrew Clark	0029.10	2973

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EXAMINER	
ALI, SHUMAYA B	
ART UNIT	**PAPER NUMBER**
3771	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/627,591	CLARK ET AL.	
	Examiner	Art Unit	
	Shumaya B. Ali	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Upon reconsideration of the previous restriction requirement, Examiner considers the restriction requirement was improper; therefore the restriction requirement mailed on 6/19/06 is hereby withdrawn. Examiner apologizes for the inconvenience.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 23,24,33,35,38,39,42-44,47,48, and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Komendowski et al. US 4,036,919.

As to claim 23, Komendowski discloses a device (figs.1 and 2, 10) for increasing the bioavailability of an aerosolized active agent (col.1, lines 35-40), said device comprising a flow restrictor (fig.3, 18; col.4, lines 55 and 56) for limiting the flow of an aerosolized active agent formulation to a human patient to less than 17 liters per minute (the size of the device would inherently allow claimed flow rate, see col.3, lines 5-10), wherein the device is adapted to aerosolize the active agent formulation and wherein the active agent formulation is (i) a powder, (ii) a solution, suspension, or slurry that may be nebulized (col.1, lines 35-40, 60-68, and col. 2, lines 1-8), or (iii) suspended or dissolved in a propellant.

As to claim 24, Komendowski discloses the device of claim 23 wherein the flow restrictor comprises an orifice (27).

As to claim 33, Komendowski discloses a device (figs.1 and 2, 10) for delivering an aerosolized active agent (col.1, lines 35-40) to the lungs of a human patient, wherein said device is adapted to deliver an aerosolized active agent formulation at an inspiratory flow rate of less than 17 liters per minute (the size of the device would inherently allow claimed flow rate, see col.3, lines 5-10), wherein the device is adapted to aerosolize the active agent formulation and wherein the active agent formulation is (i) a powder, (ii) a solution suspension, or slurry that may be nebulized (col.1, lines 35-40, 60-68, and col. 2, lines 1-8), or (iii) suspended or dissolved in a propellant.

As to claim 35, Komendowski discloses wherein the device is adapted to deliver the aerosolized active agent formulation at an inspiratory flow rate of 10 liters per minute or less (see col.3, lines 5-10).

As to claim 38, Komendowski discloses a device (figs. 1 and 2, 10) for delivering aerosolized insulin to the lungs of a human patient, wherein said device comprises a flow restrictor (fig.3, 18; col.4, lines 55 and 56) to restrict an inspiratory flow rate of an aerosolized insulin formulation to less than 17 liters per minute (the size of the device would inherently allow claimed flow rate, see col.3, lines 5-10), and wherein the device is adapted to aerosolize the insulin (col.1, lines 35-40, 60-68, and col. 2, lines 1-8).

As to claim 39, Komendowski discloses wherein the inspiratory flow rate is 10 liters per minutes or less (see col.3, lines 5-10).

As to claim 42, Komendowski discloses a device (figs. 1 and 2, 10) for delivering an aerosolized active agent to the lungs of a human patient, wherein said device comprises one or more orifices (fig.3, 27) sized so that an aerosolized active agent formulation may be delivered at

an inspiratory flow rate of less than 17 liters per minute (the size of the device would inherently allow claimed flow rate, see col.3, lines 5-10), wherein the device is adapted to aerosolized the active agent formulation and wherein the active agent formulation is (i) powder, (ii) a solution, suspension, or slurry that may be nebulized, or (iii) suspended or dissolved in a propellant (col.1, lines 35-40, 60-68, and col. 2, lines 1-8).

As to claim 43, Komendowski discloses wherein the device is adapted to deliver an aerosolized insulin formulation to the lungs (col.1, lines 35-40, 60-68, and col. 2, lines 1-8).

As to claim 44, Komendowski discloses wherein the orifices are sized so that the aerosolized active agent formulation may be delivered at an inspiratory flow rate of 10 liters per minute or less (col.3, lines 5-10).

As to claim 47, Komendowski discloses a device (figs. 1 and 2) for delivering an aerosolized active agent to the lungs of a human patient, said device comprising a chamber (10) in flow communication with a mouthpiece (53); means for aerosolizing (see "gas" and "liquid" in col.1, lines 60-68, and col.2, lines 1-8) the active agent, and means for limiting (27) an inspiratory flow rate though the mouthpiece to less than 17 liters per minute (col.3, lines 5-10), whereby an aerosolized active agent formulation in the chamber may be delivered to the human patient, the active agent formulation being (i) a powder, (ii) a solution, suspension, or slurry that may be nebulized (col.1, lines 35-40, 60-68, and col. 2, lines 1-8), or (iii) suspended or dissolved in a propellant.

As to claim 48, Komendowski discloses wherein the inspiratory flow rate is limited to 10 liters per minute or less (col.3, lines 5-10).

As to claim 50, Komendowski discloses the device further comprising means for aerosolizing the active agent (see the use of "gas" and "liquid" in col.1, liens 60-68, and col.2, lines 1-8).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 25,27-29,30-32,34,36,37,40,41,45,46,49,51, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Komendowski et al. US 4,036,919.

As to claim 25, Komendowski lacks the explicit teachings of wherein the flow restrictor comprises apertures of 0.5 to 0.9 mm in diameter, however, Komendowski teaches the restrictor comprises apertures that allows a flow rate of less than 17 liters per minute, which is also claimed in the Applicant's invention, therefore, the size of the apertures inherently would have to be with the diameter ranges as claimed in order to provide the flow of less than 17 liters per minutes.

As to claim 27, Komendowski lacks the explicit teachings of wherein the flow restrictor is a valve that provides for high resistance at all flow rates except a desired flow rate range, however, Komendowski teaches a pressure release valve (see col.4, liens 60-68, and col.5, lines 1-17). It should be also recognized that Komendowski teaches the restrictor comprises apertures that allows a flow rate of less than 17 liters per minute. Therefore, the pressure release valve would operate such to yield a flow rate of less than 17 liters per minute. Therefore, the restrictor valve would inherently provide for high resistance at all flow rates except a desired flow rate of less than 17 liters per minutes.

As to claim 28, Komendowski lacks the device of claim 23 wherein the device is adapted to be used with an active agent selected from the group consisting of insulin, cyelsporin, parathyroid hormone, follicle stimulating hormone, aipha-I-antitr)sin, budesonide, human growth hormone, growth hormone releasing hormone, interferon alpha, interferon beta, growth colony stimulating factor, leutinizing hormone releasing hormone, caicitonin, low molecular weight heparin, somatostatin, respiratory syncytial virus antibody, erythropoietin, Factor VIII, Factor

IX, cereclase, cerezyrne and analogues, agonists and anlagonists thereof, however, Komendowski teaches a nebulizer, therefore teaches a broad ranges of active agent that can be adapted to be nebulized that are also within the scope of the claimed invention.

As to claims 29,31,34,36,40,45, and 51, Komendowski lacks wherein the active agent formulation is a powder and wherein the device is adapted to aerosolize the active agent. However, Applicant has not stated why a specific active agent is critical to the invention in terms of providing a specific function or solving a stated problem. Therefore, it would have been an obvious design consideration to select the active agent as claimed because the type of agent used does not affect how the device would work. Therefore, it would have been an obvious design matter to modify Komendowski to obtain the invention as specified in claims 29,31,34,36,40,45, and 51.

As to claims 30,37,41,46, and 52, Komendowski lacks wherein the active agent formulation is contained in a blister and wherein the device is adapted to receive the blister. However, Applicant has not stated why a specific active agent is critical to the invention in terms of providing a specific function or solving a stated problem. Therefore, it would have been an obvious design consideration to select the active agent as claimed because the type of agent used does not affect how the device would work. Therefore, it would have been an obvious design matter to modify Komendowski to obtain the invention as specified in claims 30,37,41,46, and 52.

As to claim 32, Komendowski lacks wherein the device is adapted to aerosolize the powder active agent formulation using compressed air. However, it has been established that the type of active agent used in the invention is a matter of design choice (see rejection cited for

claims 29,31,34,36,40,45, and 51). Since Komendowski teaches an aerosolized agent that does not specifically use the poser active agent, therefore, does not require the claimed language of "using compressed air", however, aerosolization the poser active agent formulation using compressed air is well known in the medical art (see the invention of Smith et al. US 5,740,794, col.24, lines 5-20).

As to claim 49, Komendowski lacks wherein the device is adapted to deliver an aerosolized insulin formulation in the lungs. However, Applicant has not stated why a specific active agent is critical to the invention in terms of providing a specific function or solving a stated problem. Therefore, it would have been an obvious design consideration to select the active agent as claimed because the type of agent used does not affect how the device would work. Therefore, it would have been an obvious design matter to modify Komendowski to obtain the invention as specified in claim 49.

Claims 23 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. US 5,740,794.

As to claim 23, Smith discloses a device (fig1, 10) for increasing the bioavailability of an aerosolized active agent (col.3, lines 35-50), said device comprising a flow restrictor (fig.7, 126; col.16, lines 52-60), wherein the device is adapted to aerosolize the active agent formulation and wherein the active agent formulation is (i) a powder, (ii) a solution, suspension, or slurry that may be nebulized or (iii) suspended or dissolved in a propellant (col.3, lines 35-50). Smith, however lacks the recitation of limiting the flow of an aerosolized active agent formulation to a human patient to less than 17 liters per minute, however, Komendowski in a nebulizing flow limiting system teaches that a smaller chamber may be appropriate when a flow rate of gas of

about 3 liters per minute is employed and a larger one may be appropriate with a flow rate of 10 liters per minute. Therefore, Komendowski teaches that the flow rate is a matter of design consideration that be provided based on the size of the device (see Komendowski US 4,036,919 col.3, liens 5-8). Therefore, it would have been an obvious design choice to modify Smith to obtain the flow rate as specified in claim 23.

As to claim 26, Komendowski discloses the device of claim 23 wherein the flow restrictor is a valve (fig.8, 110) that provides for decreasing resistance with increasing flow rate (see col.16, lines 52-68).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shumaya B. Ali whose telephone number is 571-272-6088. The examiner can normally be reached on M-W-F 8:30am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

3/29/07

Shamaya B. Ali
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